

**Serial No. 09/749,185****REMARKS**

The Final Office Action of December 8, 2004, has been received and reviewed. Claims 1, 3, 8, 9, 11, 14-19, 29-33 and 35 are currently pending, and all pending claims stand rejected. Applicants would thank to the Examiner for the courtesy extended in the interview of March 28, 2005. Applicants propose to amend claims 1, 8, 9, 11, 14, 33 and 35, and cancel claims 3 and 30-32 as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is requested.

**Substance of the Interview**

The Examiner provided an interview summary to the applicants' representatives for the interview with the Examiner on March 28, 2005. The interview summary provided by the Examiner indicated that Manjunath N. Rao, Ph.D., Allen Turner, and John Renes attended the interview.

The interview summary further indicated that the applicants discussed the outstanding rejections under 35 U.S.C. 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs as well as the rejections under 35 U.S.C. 102(b) and 103(a). The applicants proposed specific amendments and arguments traversing the rejections that are encompassed in the instant amendment. The interview summary further noted that the Examiner agreed to consider the amendments and arguments favorably.

The interview summary accurately describes the interview and, thus, the above statement is made in accordance with M.P.E.P. § 713.04.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claim 35 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In view of the proposed amendment to claim 35, reconsideration is requested.

Although applicants do not agree that claim 35 is indefinite, to expedite prosecution, applicants propose to amend claim 35 to recite "transforming" in place of "providing" in accordance with the suggestion of the Examiner and as discussed at the interview.

Reconsideration and withdrawal of the indefinite rejection of claim 35 are requested.

Serial No. 09/749,185

**Rejections under 35 U.S.C. § 112, first paragraph**

Claim 30 stands rejected under 35 U.S.C. § 112, first paragraph, for assertedly lacking enablement. Claim 30 has been canceled rendering the rejection thereof moot.

**Rejections under 35 U.S.C. § 102**

Claims 1, 3, 8-9, 11, 14-15 and 30-33 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Kawamoto et al. Claims 3 and 30-32 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the remaining rejections as set forth herein.

Claims 1, 8-9, 11, 14-15 and 33 cannot be anticipated since Kawamoto et al. does not disclose each and every element of any of the claims. As discussed at the interview, the proposed amendments to claim 1 recite in part transforming or transfecting a *Streptomyces* bacterium with an expressible polynucleotide encoding a heterologous SsgA that is not present in the *Streptomyces* bacterium in nature, the heterologous SsgA comprising at least one of SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7 and SEQ ID NO: 9, said *Streptomyces* bacterium lacking detectable endogenous SsgA during submerged culture. Support for amended claim 1 is found, *inter alia*, at page 6, lines 12-14, page 13, lines 13-14, page 14, lines 3-13, and SEQ ID NOS: 3-7 of the Sequence Listing of the as-filed specification. At the interview, the applicants' representatives discussed adding language directed towards SEQ ID NOS: 3-6. Upon further review of the sequence identifiers, SEQ ID NOS: 3, 5, 7 and 9 correspond to the amino acid sequences and have been added to the claims, while SEQ ID NOS: 4 and 6 are directed towards nucleotide sequences.

Kawamoto et al. does not disclose transforming or transfecting a *Streptomyces* bacterium with an expressible polynucleotide encoding a heterologous SsgA that is not present in the *Streptomyces* bacterium in nature as recited in amended, independent claim 1. Rather, Kawamoto et al. states

*ssgA* gene showed hybridization to two bands, approximately 3.0 and 1.4 kb, of *Bam*HI-*Bgl*II digested DNA in *S. lividans*. (lane 8). The gene also hybridized to two bands of 1.9 and 1.1 kb with *Bam*HI-*Pst*I digested DNA (lane 9) in the organism. *S. coelicolor* digested with *Bam*HI-*Bgl*II showed two bands of hybridization with sizes 2.7 and 1.2 kb (lane 10), and 1.5 and 0.9 kb with the

Serial No. 09/749,185

*Bam*HI-*Pst*II digest (lane 11). The strength of the hybridization signal was much lower in *S. lividans* and *S. coelicolor* than for *S. griseus* with the high stringency hybridization conditions employed in these experiments. These data suggest that the *ssgA* gene is present in *S. coelicolor* and *S. lividans*, but in a lesser homology to that of *S. griseus*.

(Kawamoto et al., page 145). Accordingly, the Streptomyces bacterium of Kawamoto et al. does have the SsgA present in nature and, thus, cannot anticipate amended claim 1.

Kawamoto et al. also does not disclose the Streptomyces bacterium lacking detectable endogenous SsgA during submerged culture of amended claim 1, or an Actinomycete bacterium lacking a detectable endogenous SsgA of amended claim 33 as required to establish anticipation. Rather, Kawamoto et al. indicates that "[i]n this medium [e.g., DM1], both organisms [referring to *S. griseus* wildtype and *S. lividans*] normally grow as branched mycelia and sporulate." (*Id.* at 148). Kawamoto et al. further indicates "the *ssgA* gene product, a 15.8 kDa acidic protein, acts in two ways; as a positive effector of cell division and as a negative effector of sporulation." (*Id.* at 148). Thus, as *S. griseus* wildtype and *S. lividans* of Kawamoto et al. both sporulate, they both lack a detectable endogenous SsgA which, according to Kawamoto et al., acts as a negative effector of sporulation. Since Kawamoto et al. does not disclose a Streptomyces bacterium or an Actinomycete bacterium lacking a detectable endogenous SsgA during submerged culture, Kawamoto et al. cannot anticipate amended, independent claims 1 or 33.

Kawamoto et al. further cannot anticipate amended claims 1 or 33 since Kawamoto et al. does not disclose transforming or transfecting a Streptomyces bacterium with an expressible polynucleotide encoding a heterologous SsgA that is not present in the Streptomyces bacterium in nature as recited in amended claim 1 or transforming an Actinomycete bacterium lacking a detectable endogenous SsgA with a nucleic acid encoding a heterologous SsgA as recited in amended claim 33. Kawamoto et al. discloses that a DNA fragment from *S. griseus* was transformed into *S. griseus* and *S. lividans*. The introduction of the DNA fragment from *S. griseus* into *S. griseus* is not a heterologous SsgA. With respect to the introduction of the DNA fragment of *S. griseus* into *S. lividans* of Kawamoto et al., Kawamoto et al. indicates that the genomic insert has sustained some rearrangements during the course of cloning and further states that an approximate 300 base pair region located at the left end of the pNY22 insert DNA could

**Serial No. 09/749,185**

have originated from an unrelated genomic DNA. (*See, Id.* at page 146). Thus, some rearranged sequence was placed into *S. lividans*, not the *S. griseus* ssgA gene.

Further, since the *S. lividans* strain used by Kawamoto et al. comprises ssgA and amended claim 1 recites that the *Streptomyces* bacterium lacks detectable endogenous SsgA during submerged culture, amended claim 1 further cannot be anticipated.

As dependent claims 8-9, 11 and 14-15 include the elements of base claim 1, dependent claims 8-9, 11 and 14-15 are not anticipated, at the very least, as depending from novel base claim 1.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 8-9, 11, 14-15 and 33 are requested.

#### **Rejections under 35 U.S.C. § 103**

Claims 16-19 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Kawamoto et al. as applied to claims 1, 3, 8-9, 11, 14-15 and 30-33 and further in view of the common knowledge in the art for making recombinant bacterium and expressing heterologous proteins. Applicants respectfully traverse the rejections as hereinafter set forth.

Claims 16-19 depend from nonobvious base claim 1 and, thus, include the elements of base claim 1. Since the cited references do not teach or suggest teach and every element of amended claim 1, the cited references also cannot teach or suggest each and every element of claims 16-19 which include the elements of amended claim 1 as required for obviousness.

Reconsideration and withdrawal of the obviousness rejections of claims 16-19 are requested.

#### **ENTRY OF AMENDMENTS**

The proposed amendments to claims 1, 8, 9, 11, 14, 33 and 35 should be entered since the proposed amendments are supported by the as-filed specification, do not add any new matter and should not require a further search. For instance, submitted herewith is an internal communication from the Office indicating that SEQ ID NOS: 3, 5, 7 and 9 were searched. Further, the proposed amendments adopt suggestions of the Examiner, comply with requirements as to form, *i.e.*, by removing indefiniteness issues, and as discussed at the interview, should place

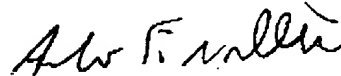
**Serial No. 09/749,185**

the application in condition for allowance. Should the Examiner determine that the proposed amendments do not place the application in condition for allowance, entry is requested since it will simplify issues for appeal.

### **CONCLUSION**

In view of the foregoing remarks and proposed amendments, the applicants submit that the claims should be in condition for allowance and a notice of allowance is solicited. Should questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Andrew F. Nilles  
Registration No. 47,825  
Attorney for Applicants  
TRASKBRITT, PC  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

Date: April 27, 2005

Attachment: copy of email

AFN  
Document in ProLaw